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COMMENTS:

DOES NOT CONTAIN CBI

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348006



SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL
NORTH AMERICA



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Via Certified Mail

August 15, 2012



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TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: TSCA Section 8(e) Notification: Amino-functional Alkoxysilanes (CAS No. 474530-85-3)

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC)¹ submits, on behalf of its member companies, the following preliminary information concerning an ongoing *in vitro* mammalian chromosome aberration test with amino-functional alkoxysilanes. Neither SEHSC, nor any member company, has made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings.

Chemical Substances

474530-85-3 Amino-functional Alkoxysilane

Study

In vitro Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Amino Functional Alkoxysilanes

¹ SEHSC is a not-for-profit trade association whose mission is to promote the safe use of silicones through product stewardship and environmental, health, and safety research. The Council is comprised of North American silicone chemical producers and importers.

CONTAINS NO CBI

Summary

The test article was evaluated for clastogenicity in Chinese Hamster V79 cells in accordance with O.E.C.D. Guidelines for Testing of Chemicals test guideline number 473. Under the conditions of this study the test article was determined to be clastogenic.

Details

Study Design

An asynchronous population of Chinese Hamster V79 cells in exponential growth was tested with and without metabolic activation. Cells were exposed for 4 hours to the following concentrations of test article (1.0, 2.5, and 5.0 $\mu\text{L}/\text{mL}$) without activation and (0.2, 0.3, and 0.4 $\mu\text{L}/\text{mL}$) with activation (S-9 mix in serum free media). The solvent utilized was acetone. Positive controls were conducted with the experiment and consisted of direct-acting (without activation) and indirect-acting (with activation) clastogens. At least 200 metaphases per concentration were evaluated for cytogenetic damage.

Results

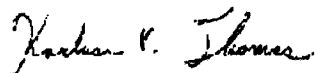
Chinese Hamster V79 cells were evaluated after exposure to the test substance at concentrations of 1.0, 2.5 and 5.0 $\mu\text{L}/\text{mL}$ without metabolic activation. The highest concentration showed an aberration incidence of 6.0%, a value above the test facility's historical range of the negative control (0.0% - 4.0%) and the concurrent solvent control (3.5%). Increases in aberration rates of 7.5%, 5.3%, and 8.7% were observed in Chinese Hamster V79 cells following exposure to the test substance at 0.2, 0.3 and 0.4 $\mu\text{L}/\text{mL}$ with metabolic activation, respectively. Therefore under the conditions of this assay, the test article was considered to be clastogenic.

Action

A copy of the final report "*In vitro* Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Amino Functional Alkoxysilanes (CAS No. 474530-85-3)" will be provided when it is available.

If you have any questions concerning this submission, please contact me at (703) 788-6570, kthomas@sehsc.com, or at the address provided herein.

Sincerely,

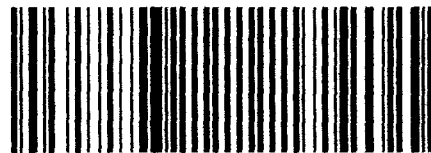


Karluss Thomas
Executive Director



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